PATENT ATTORNEY DOCKET: 62805.000041



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number

10/815,995

Confirmation No.:

7292

Applicant

Edward M. SELLERS et al.

Filed

April 2, 2004

Title

THERAPEUTIC AND DIAGNOSTIC METHODS DEPENDENT

ON CYP2A ENZYMES

TC/Art Unit

: 1614

Examiner:

Unassigned

Docket No.

62805.000041

Customer No.

21967

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants are submitting herewith copies of the references listed on the attached Form PTO-SB/08A (modified) for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

The subject application is a Divisional of U.S. Application No. 09/584,669 (Attorney Docket No. 62805.000020), filed June 1, 2000. In accordance with 37 C.F.R. § 1.98(d), patent documents and published articles which were cited in the prior application are listed on the accompanying Form PTO-SB/08A, but copies of these documents are not enclosed as they were provided in the prior application. However, copies will be forwarded at the request of the Examiner.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action and within three months of the

filing date of the application. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: July 2, 2004

Hunton & Williams LLP Intellectual Property Department 1900 K Street, N.W. Suite 1200 Washington, DC 20006 (202) 955-1500 (telephone) (202) 778-2201 (facsimile)

JTP/sdw

PTO/SB/08A (10/01) (modified) • U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

10/815.995 Substitute for form 1449A/PTO **Application Number Filing Date** April 2, 2004 INFORMATION DISCLOSURE Edward M. SELLERS et al. **First Named Inventor** STATEMENT BY APPLICANT **Art Unit** 1614 (use as many sheets as necessary) Unassigned **Examiner Name** of 2 **Attorney Docket Number** 62805.000041 **Sheet** 1 U.S. PATENT DOCUMENTS Pages, Columns, Lines, DOCUMENT NUMBER *Examine Cite Where Relevant Passages or Name of Patentee or **Publication Date** Relevant Figures Appear Initials No. Applicant of Cited Document Number - Kind Code (if known) MM-DD-YYYY 08-05-1997 Modi et al. US 5653987 1. Viner US 5760049 06-02-1998 2. FOREIGN PATENT DOCUMENTS Pages, Columns, FOREIGN PATENT DOCUMENT Lines, Where TRANSLATION Relevant Passages Country Number - Kind Code Cite **Publication Date** or Relevant Figures Name of Patentee or (if known) Code: Initial No. MM-DD-YYYY Applicant of Cited Document Appear YES П Jeffrey et al. 95/34679 12/21/1995 3. WO **NON-PATENT LITERATURE DOCUMENTS** Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the TRANSLATION item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue *Examine number(s), publisher, city and/or country where published Initials No. YES NAKAJIMA, M. et al., "Characterization of CYP2A6 involved in 3'-hydroxylation of continine in 4. human liver microsomes," J. Pharmacol. Exp. Therap., (1996) Vol. 277, No. 2, pp. 1010-1015 NAKAJIMA, M. et al., "Role of human cytochrome P4502A6 in C-oxidation of nicotine," Drug 5 Metabol. Dospos., (1996) Vol. 24, No. 11, pp. 1212-1217 TSUJIMOTO, A. et al., "Potent inhibitory action of pilocarpine on hepatic drug metabolism," Jpn. J. 6. Pharmacol., (1972) Vol. 22, No. 5, 736 TSUJIMOTO, A. et al., "A study of the nature of pilocarpine on hepatic drug-metabolizing 7. enzymes," Biochem. Pharmacol., (1977) Vol. 26, No. 21, pp. 2072-2074 FOTH, H.et al., "Nicotine metabolism is isolated perfused lung and liver of phenobarbital-and 8. benzoflavone-treated rats," Arch. Toxicol., (1991) Vol. 65, No. 1, pp. 68-72 **EXAMINER SIGNATURE** DATE CONSIDERED *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08A (10/01) (modified)

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Sheet

Application Number	10/815,995
Filing Date	April 2, 2004
First Named Inventor	Edward M. SELLERS et al.
Art Unit	1614
Examiner Name	Unassigned
	62805.000041
Attorney Docket Number	02003.000041

NON-PATENT LITERATURE DOCUMENTS

NON-1 AT EXTERNAL title of the article (when appropriate), title of the			TRANSLATION	
*Examiner	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	YES	NO
	9.	KYEREMATEN, G. A. et al., "Metabolism of nicotine by hepatocytes," Biochem. Pharmacol., (1990) Vol. 40, No. 8, pp. 1747-1756		
	10.	YAMAZAKI, H. et al., "Cytochrome P450 sE1 and 2A6 enzymes as major catalysts for metabolic activation of N-nitrosodialkylamines and tobacco-related nitrosamines in human liver microsomes," Carcinogenesis (1992) Vol. 13, No. 10, pp. 1789-1794		
	11.	CAPLUS, DN 120:238085, Garnitskij et al., SU 1803032 A1, 1993/03/23, English abstract with notes from oral translation		
	12.	MAYS et al., Methoxsalen is a potent inhibitor of caffeine in humans, Clin. Pharmacol. Ther., 42:621-626 (1987)		
	13.	MAENPAA et al., "Metabolic interactions of methoxsalen and coumarin in humans and mice," Biochem. Pharmacol., 48(7), (1994), 1363-9		
	14.	BENOWITZ, N. L. et al., "Deficient C-Oxidation of nicotine," Clinical Pharmacol. And Therap., 57(5):590-594 (1995) (Abstract)		
	15.	Copy of International Search Report of PCT/CA98/01093, August 1999		

EXAMINER SIGNATURE

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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.